DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: PROLIA
Patent Nos. 7,411,050; 7,449,185;
6,740,522; 7,527,790; and 7,097,834
Docket Nos. FDA-2011-E-0014
FDA-2010-E-0657
FDA-2010-E-0660
FDA-2010-E-0656
FDA-2010-E-0659

APR 27 2011

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 7,411,050; 7,449,185; 6,740,522; 7,527,790; and 7,097,834, filed by Amgen Inc., under 35 U.S.C. § 156. The human biological product claimed by the patents is PROLIA (denosumab), which was assigned biologics license application (BLA) No. BL125320.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The BLA was approved on June 1, 2010, which makes the submission of the patent term extension application on July 27, 2010, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Avenue N.W.
Washington, DC 20001